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DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

4298 Elysian Fields Avenue
New Orleans, LA 70122
Telephone (504) 589-7166
Fax (504) 589-4657

May 14, 1997

WARNING LETTER NO. 97-NOL-45**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Mr. William M. Halbrook
Radiology Manager
King's Daughters Hospital
Highway 51 North
P. O. Box 948
Brookhaven, MS 39601

Dear Mr. Halbrook:

Your facility was inspected on May 8, 1997, by a representative of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, *Code of Federal Regulations (CFR)*, Part 900.12, as follows:

- The medical physicist had neither a state license nor a state approval, nor board certification, and did not meet the alternative requirement (education, training, and experience): [REDACTED]

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of the deficiency that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- **impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.**
- **suspend or revoke a facility's FDA certificate for failure to comply with the Standards.**

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- **seek an injunction in federal court** to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

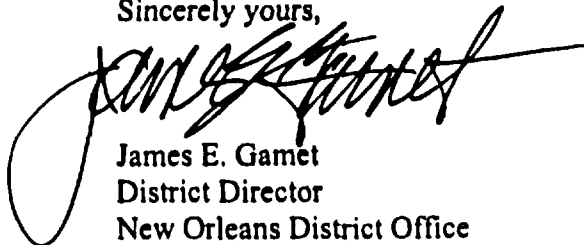
- the specific steps you have taken to **correct** the noted violation;
- each step your facility is taking to **prevent the recurrence** of similar violations;

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and state the time within which the correction will be completed.

Please send your response to Nicole F. Hardin, Compliance Officer, Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, LA 70122.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. Hardin at (504) 589-7166.

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Gamet", is written over the typed name and title.

James E. Gamet
District Director
New Orleans District Office

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